

REMARKS

Amendments

Paragraph [0033] of the specification is amended to be consistent with paragraph [0031]. Paragraph [0077] is amended for consistency with the specification. Paragraphs [0090] and [0094] are amended for consistency with structure and nomenclature used by the manufacturer as would be readily apparent to persons skilled in the art.

Claim 23 was missing from the specification as filed and for clarity is hereby cancelled. Claim 24 is amended for proper antecedent basis. Claims 35 and 36 are amended to clearly identify diameters recited in the claims.

Claims 37-47 are sought to be added. Claims 37 and 38 recite alternative embodiments supported throughout the specification. Claims 39-41 and 44 recite the product in a product by process format and are supported by, for example, original claim 26 and the examples. Because product by process claims are drawn to a product, applicants submit that the claims fall within the invention encompassed by the currently pending claims. New Claims 42-44 are supported by the specification at, for example, page 23, lines 21-22 (see paragraph [0053] of published application No. 2004/0093008 A1). New claims 45 and 46 are supported by the specification at, for example, page 17, lines 18-20 (see paragraph [0035] of published application No. 2004/0093008 A1). Claim 46 is supported by the specification at, for example, page 34, lines 13-20 (see paragraph [0086] of published application No. 2004/0093008 A1). Claim 47 recites a catheter comprising the claimed catheter balloon and is supported throughout the specification.

Election

Applicants acknowledge the election of species. Further, as noted by the Examiner, an Information Disclosure Statement listing the references cited in the specification is filed herewith for proper consideration.

Claim Rejections

The present claims are directed to catheter balloons and catheters including the balloons. According to the claims, the catheter balloon is shrunk while being axially restrained. That is, during the step of shrinking the balloon, the ends are clamped, reducing or preventing axial shrinkage of the tube, but allowing radial shrinkage. See, for example, Figure 1 and the specification at page 17, lines 10-12 and 25-27; page 32, lines 6-9; and page 33, lines 2-4 and 18-20. Optionally, there can be some controlled decrease or increase in length during shrinking, facilitated by restraining axial movement. Using prior techniques, balloons are shrunk without constraining the ends. As a result, shrinkage is not controlled and occurs not only radially, decreasing the diameter of the balloon, but also axially (sometimes referred to as longitudinally), resulting in a shortening of the tube of which the balloon is a part and an increase in wall thickness of the balloon. By axially restraining the balloon during the shrinking step, the diameter of the balloon can be reduced by a greater amount than can be achieved without axial restraint, for example by about 50% or even more. Several advantages are realized in the resultant catheter, as described in the specification and/or the declaration from the inventor submitted herewith. For example:

- Reduction of the amount of wall thickening in the shrunk balloon;
- For catheter balloons with an outer diameter of less than about 2 mm and prepared from commonly utilized materials, a reduced profile is readily achieved and little or no folding is required when the balloon is attached to the catheter and prepared for insertion;
- In larger catheter balloons where folding may be required, the degree of folding is reduced and a reduced profile realized such that there is no overlap of adjacent folds about themselves, thus reducing the overall size of the catheter to facilitate insertion while reducing the tendency to damage vessels into which it is inserted; and
- During inflation of the balloon, there is decreased axial elongation, allowing for a more consistent balloon size.

These advantages are not realized by the prior art.

The Office Action rejects claims 1-19, 35 and 36 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 7,108,826 to Wang et al. (Wang). Because Wang does not teach each and every limitation of claims 1-19, 35 and 36, a *prima facie* showing of anticipation has not been established, and Applicants respectfully traverse the rejection.

To anticipate a claim, a reference must teach every element of the claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). (“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”) See MPEP § 2131. In the present application, Wang fails to disclose each and every claim element. In particular, Wang fails to disclose axial restraint during shrinkage. This is required by independent claim 1 (“axially restrained-shrunk”), claim 11 (“axially restrained shrinkage”), and claim 37 (“heating the balloon while axially restraining”).

The Office Action states that “Wang et al teach that the balloon and balloon shrinking process are conducted by known methods including maintaining a distance between ends as well as increasing the distance between ends as instantly claimed. . . (Col. 8, Examples, Figures, Table 1.)” Applicants submit that this is not correct. Wang teaches that:

The balloon shrinking process is similar to that described in U.S. Patent No. 5,348,538 for balloons of non-compliant material such as PET.

(Wang col. 8, lines 33-46.) There is no disclosure of “maintaining a distance between ends” nor “increasing the distance between ends” during the shrinking step. In fact, U.S. Patent No. 5,348,538 specifically states that the balloon shrinks axially as well as radially during the shrinking process:

The final process that the assembled balloon catheter must undergo is the annealing technique. The entire balloon catheter is submerged in water or air at a temperature in the range of 25°-100° Centigrade for 3-180 minutes. The preferred temperature range being 65°-80° Centigrade. It should be understood that the temperature and time required in this annealing process depends upon the size of the balloon that is being processed. This annealing *process causes the length and the diameter of the balloon to decrease and the wall thickness to increase.*

(U.S. Patent No. 5,348,538, col. 11, lines 47-59, emphasis added)

Likewise, the examples in Wang do not disclose restraining the ends during shrinking. For example, the examples state only that balloons are “shrunk by dipping in a 80°C water bath for 5 minutes.” (Example 2, col. 9, lines 47-49; see also Example 4, col. 10, lines 1-2; Example 10, col. 11, lines 1-2). Because this process is identical to that of U.S. Patent No. 5,348,538, a similar decrease in length is expected.

Accordingly, Wang does not disclose each and every limitation of claims 1-19, 35 and 36, the requirements for *prima facie* anticipation have not been met and the rejections under 35 U.S.C. § 102(e) should be withdrawn.

Claims 20-25 are rejected under 35 U.S.C. § 103(a) as obvious over Wang in view of U.S. Patent No. 6,946,174 to Chen (Chen). Applicants respectfully traverse.

Among other things, in order to render an invention obvious, the prior art references when combined must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 214. The combination of Wang and Chen fails to teach all limitations of claims 20-25 and the Office Action therefore fails to render the claims *prima facie* obvious.

Claim 20 is an independent claim and recites

A compliant or semi-compliant catheter balloon for inflation to a pressure of between P_1 and P_2 , wherein the balloon is formed from a polymer that is crosslinked such that the balloon has a reduced compliance in a pressure range of 70% of P_2 up to P_2 .

Claims 21-25 all depend ultimately from claim 20. The Office Action states that “[t]he teachings of Wang et al are discussed above.” However, nowhere does the Office Action address the limitation that “the balloon has a reduced compliance in a pressure range of 70% of P_2 up to P_2 ” as required by claim 20. Chen is cited only as teaching the use of cross-linked thermoplastic polymer materials and adds nothing to Wang to correct this deficiency.

Accordingly, neither Wang nor the combination of Wang and Chen teaches every element of the claimed invention and the rejection under 35 U.S.C. § 103(a) should be withdrawn.

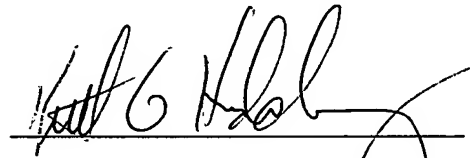
Conclusion

All of the stated grounds of objection and rejection are believed to have been properly overcome, traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicant believes that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. An early notice indicating the allowability of claims 1-22, 24, 25 and 35-47 is respectfully requested.

The Examiner is respectfully requested to contact Applicant's undersigned Representative if necessary to place the application in condition for allowance.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read 'Keith G. Haddaway', is written over a horizontal line.

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